

*Citation for published version:*

Ellett, L & Chadwick, P 2021, 'Recommendations for monitoring and reporting harm in mindfulness for psychosis research', *British Journal of Psychiatry*, vol. 219, no. 6, pp. 629-631. <https://doi.org/10.1192/bjp.2021.98>

*DOI:*

[10.1192/bjp.2021.98](https://doi.org/10.1192/bjp.2021.98)

*Publication date:*

2021

*Document Version*

Peer reviewed version

[Link to publication](#)

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**Recommendations for monitoring and reporting harm in mindfulness for psychosis  
research.**

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## **Recommendations for monitoring and reporting harm in mindfulness for psychosis research.**

### **Summary**

There is increasing interest in potential harmful effects of mindfulness-based interventions (MBIs). In relation to psychosis, inconsistency and shortcomings in how harm is monitored and reported are holding back our understanding. We offer eight recommendations to help build a firmer evidence base on potential harm in mindfulness for psychosis.

**Keywords:** Mindfulness; psychosis; harm; schizophrenia; adverse events.

One of the most significant recent developments in the field of psychotherapy has been the emergence of mindfulness-based interventions (MBIs). In relation to psychosis, MBIs were slow to develop in large part because of concern that people with psychosis are particularly vulnerable to harmful effects arising from mindfulness practice<sup>1</sup>.

### **Operationalising harm in psychotherapy research**

Harm in psychotherapy research has traditionally been defined as the occurrence, following an intervention, of a deterioration in symptoms or functioning, which is sustained, likely to have been caused by the intervention and more severe than it would have been had the individual not received the intervention<sup>2</sup>. This definition highlights two immediate complexities in defining harm in psychotherapy. First, a proportion of people with mental health conditions will experience a deterioration in symptoms with or without an intervention, so it is important to establish a baseline rate of deterioration. Randomised controlled trials (RCTs) are particularly useful in this regard, as the inclusion of a control arm

provides a valid point of comparison from within the same clinical setting and timeframe.

Second, a deterioration means more than simply a change in score – to determine the clinical significance of a change in symptoms or functioning it is helpful to know the minimal clinically important difference (MCID) for any given outcome measure.

A second approach to operationalising harm that is commonly applied in RCTs is to report the occurrence of both serious adverse events (SAEs), defined by the World Health Organisation as life-threatening or fatal occurrences, and adverse events (AEs), defined as untoward events experienced by study participants. SAEs and AEs may or may not be caused by the intervention. In a review of the available research on harm in mindfulness-based psychotherapies across a range of conditions (but not psychosis), Baer et al report that AEs or SAEs occur in 0% to 10.6% of research participants, and are no more common in mindfulness-based psychotherapies than in comparison conditions<sup>2</sup>.

A third approach to operationalising harm has been to consider indirect, or proxy indices of harm, such as study drop-out rate – the argument being that drop-out rates would be higher in psychotherapies experienced as unsafe by patients.

### **Is mindfulness for psychosis harmful?**

The literature on mindfulness-based therapies for psychosis is growing fast. An evidence base comprising more than 20 randomised studies (see Jensen et al for the most recent meta-analysis<sup>3</sup>), alongside numerous uncontrolled studies, evidences a range of clinical benefits of mindfulness for psychosis, including reduced negative symptoms and levels of depression, and enhanced psychological quality of life<sup>3</sup>. Whilst these randomised studies do not suggest that mindfulness for psychosis is harmful, a closer look at how harm is operationalised, monitored and reported in mindfulness for psychosis research reveals

some critical shortcomings that make it impossible to provide a data-driven answer to the question is mindfulness for psychosis harmful? We offer below eight recommendations (summarised in Table 1) on how harm should be operationalised, monitored and reported, to strengthen the evidence base on potential harm in mindfulness for psychosis research.

### **Recommendations for reporting of harm**

First, whilst uncontrolled research studies were pivotal to the development of mindfulness for psychosis, priority should be given to findings from RCTs when drawing generalisable conclusions about harm. The discipline in RCTs of applying a common set of study inclusion and exclusion criteria within a standardised recruitment protocol, combined with the inclusion of a control arm and random treatment allocation, provides a valid point of comparison from which to understand observed levels of harm in those receiving mindfulness for psychosis. Whilst uncontrolled studies will always be useful in flagging important potential issues of risk and harm, and in ongoing therapy development, they do not provide a solid basis for drawing firm conclusions about harm in mindfulness for psychosis.

Second, there are inconsistencies in reporting of SAEs. All future studies should state explicitly the number of SAEs by study arm; if there were none, then this should be stated explicitly. Whilst this is already a recommendation in reporting of trials it is not always applied in the MBI for psychosis literature. Also, there is some confusion about what constitutes a SAE in mindfulness for psychosis research. For example, in one study a participant death was not reported as a SAE because it was attributed to natural causes. Crucially, a SAE is defined by the untoward event itself and not by degree of imputed causal connection with study participation. Whilst it is informative to include indications of likely

degree of connection between a life-threatening or fatal occurrence and study participation, it always remains a serious adverse event and should be reported as such.

Third, there is lack of clarity around reporting of hospital admission. As with other SAEs, it is sometimes simply not reported on - does this mean it was robustly monitored and did not occur, or was not monitored? Harm in psychotherapy is such an important issue that clarity is essential. Data should minimally include the number of participants in each arm who were hospitalised – if there were none in a study arm, then this should be stated explicitly. If admissions were not monitored, then this should be stated explicitly as a study limitation. Where applicable and possible, data on hospital admissions might be supplemented by data on usage of crisis or home treatment teams.

Further inconsistency can arise in trials of MBIs for psychosis that use rehospitalisation rate as an outcome measure. Authors typically report admission rates as clinical outcomes but not also as adverse events. This substantially distorts reported rates of adverse events in mindfulness research. Selecting an adverse event as a study outcome does not obviate the need to also report it as an adverse event. Hospital admissions should always be reported as adverse events as is done in non-psychotherapy research.

Fourth, whilst real-world practical constraints mean it is not possible to monitor all potential adverse events, what is practicable is for researchers to follow Jacobsen et al<sup>4</sup> in stating clearly in their Trial Protocol those adverse events which were deemed particularly relevant to the trial, specifying how these were monitored (e.g. review of case notes), and giving detailed descriptions of any such untoward events that did occur.

Fifth, researchers are encouraged to consider using a standardized patient-reported side effect questionnaire in trials of MBIs, as is done in trials of medication. None of the

trials included in the most recent meta-analysis<sup>3</sup> of MBIs for psychosis did so. Side effects are distinct from adverse events and will occur in all psychotherapies. Recording subjective side effects will broaden understanding of potential harm in MBIs for psychosis.

Sixth, whilst studies increasingly seek to contextualise benefits of MBIs by reporting the number of participants who showed a clinically important improvement on measures of psychological functioning, it is rare for studies to report how many participants experienced a clinically important *deterioration*. None of the randomised trials of a MBI for psychosis included in the most recent meta-analysis<sup>3</sup> of MBIs for psychosis reported data across all study arms on clinically important deterioration on the primary measure of psychological functioning – and we have found only one RCT published since then that included data on clinically important deterioration on the primary outcome measure across all study arms<sup>5</sup>. Whenever possible, clinically important symptom deterioration by study arm should be reported in all future studies.

Seventh, whilst drop-out occurs for many reasons, it can be a useful indirect index of harm. CONSORT diagrams show *study* drop out – the number of participants who did not provide post-intervention or follow-up data. However, a participant who ceased attending therapy yet still provided post-intervention assessment data would not be recorded as a study drop-out. It would be useful for future studies to report not only study drop-out (including, where known, the cause of drop out), but also therapy non-completion rates as determined against a pre-set number of sessions (e.g. attending minimally 50% of sessions).

Finally, it will be important in future studies to ensure meaningful public and patient involvement (PPI) in research assessing harm. Studies are encouraged to state explicitly if

and how PPI input contributed to specific decision making around how harm was operationalised and monitored.

In conclusion, there is a pressing need to improve monitoring and reporting of harm in mindfulness for psychosis research – indeed, in the wider literature on MBIs – in order to develop a fuller understanding of both beneficial and harmful effects.

**Table 1. Summary of recommendations.**

Criteria	Recommendations
1. Study Design	i.Data from randomised controlled trial should be prioritised when drawing generalisable conclusions about harm in mindfulness for psychosis research.
2. Serious Adverse Events	i.All life-threatening and fatal occurrences should be reported as serious adverse events, regardless of degree of causal connection with study participation. ii.If there were no SAEs, this should be clearly stated. iii. If SAEs were not monitored, this should be listed as a study limitation.
3. Hospital Admissions	i.Hospital admissions should always be reported as adverse events, even when hospitalisation is a study outcome. ii. If there were none, this should be clearly stated. iii.Could be supplemented with data on usage of crisis services if possible. iv. If they were not monitored, this should be listed as a study limitation.
4. Adverse Events	i.List which instances of less serious adverse events were monitored ii.List how they were monitored (e.g. case note review). iii.Provide detailed descriptions of any adverse events that occur.
5. Side effects	i.Include standardised patient-reported measure of side effects
6. Symptom Deterioration	i.All Instances of clinically meaningful deterioration in symptoms or psychological functioning should be reported.
7. Drop Out	i.Report study drop out, and reason for drop out (including direct or indirect link to harm), by treatment arm. ii.Report separately drop out and non-completion of therapy.
8. Public & Patient Involvement	i.Ensure meaningful PPI in decision-making about how harm is operationalised and monitored.

**Author contributions.** Both authors contributed equally to all aspects of the manuscript. All authors have approved the final version to be published and agree to be accountable for the accuracy and integrity of the work.



**Declaration of interest:** None.

**Funding Statement:** This research received no specific grant from any funding agency, commercial or not-for-profit sectors.

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